STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner

Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Healthcare Quality And Safety Branch

August 22, 2018

Susan Cordeau, Director Performance Improvement
Waterbury Hospital
64 Robbins Street
Waterbury, CT 06721

Dear Ms. Cordeau:

This is an amended edition of the violation letter originally dated August 15, 2018.

Unannounced visits were made to Waterbury Hospital on commencing on April 23, 2018 and concluding on June 4, 2018 by representatives of the Facility Licensing and Investigations Section of the Department of Public Health for the purpose of conducting multiple investigation.

Attached are the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut which were noted during the course of the visits.

An office conference has been scheduled for September 11, 2018 at 1:00PM in the Facility Licensing and Investigations Section of the Department of Public Health, 410 Capitol Avenue, Second Floor, Hartford, Connecticut. Should you wish to retain legal representation, your attorney may accompany you to this meeting. Please be prepared to discuss those violations Identified with an asterisk.

You may wish to dispute the violations and you may be provided with the opportunity to be heard. If the violations are not responded to by August 29, 2018 or if a request for a meeting is not made by the stipulated date, the violations shall be deemed admitted.

Please prepare a written Plan of Correction for the above mentioned violations to be presented at this conference.

Each violation must be addressed with a prospective Plan of Correction which includes the following components:

1. Measures to prevent the recurrence of the identified violation, (e.g., policy/procedure, inservice program, repairs, etc.).
2. Date corrective measure will be effected.
3. Identify the staff member, by title, who has been designated the responsibility for monitoring the individual plan of correction submitted for each violation.
4. Alternate remedies to violations identified in this letter may be discussed at the office conference. In addition, please be advised that the preparation of a Plan of Correction and/or its acceptance by the Department of Public Health does not limit the Department in terms of other legal remedies, including but not limited to, the issuance of a Statement of Charges or a Summary Suspension Order and it does not preclude resolution of this matter by means of a Consent Order.

DATES OF VISIT: Commencing on April 23, 2018 and Concluding June 4, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

Should you have any questions, please do not hesitate to contact this office at (860) 509-7400.

Respectfully,

Susan Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section

SHN:mb

Complaint #23212, 23209, 23128, 22988, 23007, 22977, 22970, 22923, 22697, 22373, 22163, 21976, 21225, 21096, 23312

DATES OF VISIT: Commencing on April 23, 2018 and Concluding June 4, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(3).

1. Based on a review of the clinical record, staff interviews, and a review of the hospital's policies and procedures for one of three sampled newborn infants (Patient #22), the facility failed to obtain a physician's order that directed one type of diet and/or failed to document that education was provided regarding the use of supplementation in accordance with the hospital's policies and procedures. The findings included:
   a. Review of the clinical record identified Patient #22 was delivered on 4/23/18 at 3:19 PM. Physician's orders dated 4/23/18 at 3:35 PM directed breastfeeding with formula supplementation. Interview with the Director of Women's Health Services on 4/27/18 at 10:00 AM identified the initial diet order for the infant should have directed one feeding choice, as a medical indication for supplementation was not identified.
   b. Review of the nutritional flow sheets dated 4/24/18 and 4/25/18 indicated formula supplementation was provided. The progress notes identified Patient #22 was cluster feeding and remained irritable after nursing. Interview and review of the clinical record with the Director of Women's Health Services on 4/27/18 at 10:15 AM indicated that the clinical record failed to identify that education was provided to the mother regarding feeding behaviors and the risks of supplementation in accordance with the hospital policy. The hospital policy entitled breastfeeding directed in part that breastfeeding is the normative and optimal feeding method for infants. Formula supplementation should be avoided unless medically indicated. The policy further directed if supplementation was requested by a breastfeeding mother, she would be assessed as to the reasons for her request, educated about normal newborn feeding behaviors and requirements, counseled about the risks of supplementation to her infant, and how to protect her milk supply. The registered nurse would provide said counseling and document the information in the clinical record.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff 92)(B) and/or (i) General (6).

2. *Based on a review of the clinical record, staff interviews, and a review of the hospital's policies and procedures for one sampled patient who underwent a caesarean section (Patient #13), the facility failed to ensure an internal fetal monitor was not retained. The finding included:
   a. Review of the clinical record identified Patient #13 was admitted to the hospital on 4/2/18 at 2:21 AM at thirty eight weeks gestation with spontaneous rupture of membranes. At 7:43 AM fetal bradycardia was identified and an internal fetal scalp electrode was inserted to assess fetal well-being. Fetal bradycardia continued and Patient #13 underwent an emergency caesarean section on 4/2/18 at 7:57 AM secondary to fetal distress. Due to the emergent nature of the surgery an instrument count was not conducted. Abdominal imaging was completed at the close of the surgical case prior to the patient leaving the operating

room, per hospital procedure. The radiologist notified MD #11 thirty minutes after the case that a wire metallic object was located in the mid upper abdomen. A repeat film was completed that confirmed a retained metallic device. Patient #13 was taken back to the operating room on 4/2/18 at 11:16 AM under general anesthesia to remove a fetal scalp electrode.

Interview with MD #11 on 5/2/18 at 10:20 AM indicated abdominal imaging was conducted after the patient was closed. MD #11 left the operating room prior to obtaining the results of the abdominal film. MD #11 identified she called the family birthing center and received a verbal report from the unit secretary that the abdominal film did not reveal a retained foreign body. MD #11 indicated approximately thirty minutes after the procedure the radiologist informed her of a possible retained metallic device. After imaging was conducted a second time to confirm the foreign body, the patient was taken to the operating room for the removal of the scalp electrode. MD #11 identified that typically the scalp electrode is removed prior to the start of the cesarean section, however due the emergent nature of this case it was not. MD #11 observed the internal fetal electrode when removing the infant from the uterus and cut the wire and handed it to the scrub nurse. MD #11 then removed the scalp electrode and placed it on the lap pad. MD #11 indicated when she removed the lap pad from the patient's abdomen the electrode likely fell into the abdomen.

Interview with Surgical Technician #1 on 5/1/18 at 1:00 PM identified that an internal monitor was not part of the surgical count. Surgical Technician #1 indicated although the wire was collected she did not know that the electrode was part of the device, therefore, she did not communicate to the surgical team that it was missing.

Interview with the Vice President of Performance Improvement on 5/2/18 at 11:00 AM indicated that subsequent to the event the family birthing center count sheet was revised to include the removal of the fetal scalp electrode. The count policy was revised to direct that the physician cannot leave the operating room prior to communicating with the radiologist when imaging was conducted to ensure that a foreign body was not retained.

The hospital policy entitled Count Policy failed to identify that counts may be omitted for life threatening emergent procedures and that the patient or the practitioner cannot leave the operating room until a reading was received from the radiologist when imaging was conducted.

<u>The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (d) Medical Records and/or (e) Nursing Services (1).</u>

3. Based on clinical record reviews, review of facility documentation and interviews for one of three sampled patients (Patient #6) who were a fall risk, the facility failed to ensure an assessment was performed following an unwitnessed fall. The findings include:
   a. Patient #6 was admitted on 1/3/18 from a SNF for evaluation of increased agitation and violent behaviors. Patient #6's past medical history included diabetes, traumatic brain injury, below knee amputation, substance and alcohol abuse and major depression. The clinical record identified the patient's activity status as bathroom privileges and use of a prosthetic

leg. The clinical record identified the patient was assessed at risk for falls. A physician's order dated 1/3/18 directed safety checks every two hours.
Review of the clinical record identified on 1/6/18 safety checks was documented every two hours this included chair/bed alarm and call bell within reach. The nursing note dated 1/6/18 at 5:11AM identified the patient had stated he/she had an unwitnessed fall on 1/6/18 at approximately 1:00AM and complained of right shoulder pain. The note identified the patient was put in a reclining chair, the wheelchair removed and prosthetic leg placed in the room hall. The note further identified Patient#6 had a witnessed fall at 4:00AM, the patient was assisted back to bed, becoming increasingly agitated and refusing to stay in bed. After physician notification an order directed X-ray of the right shoulder and CT scan of the head. Review of the clinical record failed to identify documentation that the patient was assessed following the unwitnessed fall.
The CT scan of the head dated 1/6/18 reported negative findings; X-ray of the right shoulder dated 1/6/18 reported no fracture, question of joint separation and recommendation for clinical correlation. The orthopedic consult dated 1/9/18 identified right shoulder joint separation, no surgery intervention required and to wear sling.
In an interview on 4/27/18 at 11:40AM, RN#3 identified on 1/6/18 Patient #6 informed him that he/she had a fall at the end of the hall. RN#3 had noted urine on the floor in the area of where the unwitnessed fall had occurred. RN#3 further identified he put away the patient's prosthetic leg and wheelchair and could not recall if he had performed a full physical assessment. RN#3 also stated that Patient #6 knew how to turn off the bed alarm and somehow got out of the bed, retrieved the prosthetic leg and attempted to get out of the room where he was witnessed to have another fall. RN#3 further identified the patient was assisted back to bed, was verbally abusive and complained of shoulder pain.
In an interview on 4/27/18 at 2:00PM, the Risk Manager (Manager#2) indicated the facility investigation identified the patient had an unwitnessed fall at 1:00AM and a subsequent fall at 3:45AM. Manager #2 identified the post fall assessment would be located in the clinical record.
Review of the facility fall prevention policy identified in part the post fall assessment, interventions and documentation includes assessing the patient's condition and to notify the MD of the fall.

<u>The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6) and/or (l) infection control (1).</u>

4. Based on observations, facility documentation and interviews the facility failed to ensure the auto instrument washer/disinfector and ultrasonic cleaner were tested according to manufacturer guidelines. The findings include:
   a. During tour of the Central Sterile Department on 4/23/18 review of the automated washer disinfector log sheet for the test object surgical instrument (T.O.S.I.) blood soil test and the Sono check log sheet identified documentation for testing on 1/4/18, 1/12/18, 1/30/18, 2/5/18, 2/15/18, 3/5/18, 3/19/18, 4/2/18 and 4/19/18. The log sheets identified 'Pass' for

each date tested and initialed by the Central Sterile Tech manager.
In an interview on 4/23/18 at 1:40PM the Central Sterile Tech manager acknowledged that the tests should be performed weekly but has not been able to maintain this.
According to the Association for the Advancement of Medical Instrumentation (AAMI) guidelines weekly TOSI testing is required to evaluate the cleaning effectiveness of the automated instrument washers.
The facility was unable to provide a policy for testing the effectiveness of the washer/ disinfector and ultrasonic cleaner, subsequent to surveyor inquiry policies were formatted for the same.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (e) Nursing Services (1) and/or (i) General (6).

5. Based on medical record review and interviews for 1 (P#14) of 4 patient reviewed for restraint use and/or constant observation the hospital failed to ensure constant observation was provided as according to hospital policy. The findings include:
   a. Patient (P) #14 was admitted on 4/13/18 to the behavioral health unit (BHU) from the Emergency Department (ED) after expressing suicidal ideation (SI). P#14's history included prior ED visits due to SI, recent heroin and Phencyclidine (PCP) use, assaultive behavior, hyper sexuality and promiscuous behavior including prostitution. Initial and subsequent suicide risk assessments identified P#14 expressed no SI and remained safe with checks every 15 minutes. P#14 remained on checks every 15 minutes until 4/19/18 at which time P#14 was placed on constant observation (CO) after physically assaulting a staff member. During interviews with Register Nurse (RN) #1,Security Officer (SO) #1, Behavioral Health (BH) Technician #1 and BH Technician #2 the staff indicated SO#1 was assigned constant observation for P#14 and was positioned outside P#14's room in the hallway. They indicated SO#1 was not observing P#14 from inside his/her room because P#14 had exhibited paranoid, accusatory, hypersexual behaviors towards staff including removing his/her clothing. P#14 remained in his/her room in bed at all times between 10:00 PM and 11:20 PM. SO#1 indicated P#14 remained within the line of sight at all times.
   Hospital Patient Observation policy indicated the purpose of a BH constant staff companion was to maintain patient safety and the safety of others. The policy further indicated when a patient was under constant observation (CO) the patient should remain within arm's reach of staff members at all times.
   In addition, although P#14's physician orders and treatment plan identified P#14 required constant observation, the treatment plan failed to indicate the rationale for modifying aspects of the hospital policy to treat P#14's individualized needs.

DATES OF VISIT: Commencing on April 23, 2018 and Concluding June 4, 2018

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (4) (A).

6. Based on observation during tour, clinical record review, and interviews, the facility failed to ensure the privacy of one patient (#8) during a psychiatric consultation. The finding includes the following:
   a. Review of Patient #8's clinical record indicated that the patient was seen in the outpatient behavioral health clinic for medication management. Review of the note dated 2/26/18 indicated that the patient was evaluated by MD #5, noted the patient was in a wheelchair and was feeling ok. The patient was alert and fully oriented, had good insight and good judgement.
   Interview with MD #5 on 4/24/18 at 11:00 AM stated when he consulted with the patient on 2/26/18, the patient's wheelchair did not fit through the doorway so he spoke to him/her while the patient was in the hallway. Interview with Patient #8 on 5/21/18 at 11:00 AM indicated that the patient knew his/her wheelchair would not fit in MD #5's office and had told this to the secretary on arrival to the clinic. Patient #8 stated he/she sat in the hallway with only his/her legs in the office and head down crying during the evaluation.
   A tour of the facility was conducted with the Director of the program who indicated that there are some doorways in the facility that are too narrow for a wheel chair and there are other open rooms on the floor that are to be used. The Director indicated that the facility protocol is for the practitioner to move to another office down the hall and that there are three that are open for use.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (3) and/or (e) Nursing service (1).

7. Based on a review of clinical records and interview, for one of three patients reviewed for pain (Patient #4), the facility failed to ensure the patient's pain was addressed. The findings include the following:
   a. Patient #4 presented to the ED on 7/28/16 at 12:42 PM after a fall with a question of a syncopal episode. The record reflected that the patient was noted to be diaphoretic, slightly confused, and complained of abdominal pain (pain rated as a 10 on a scale of 1-10 with 10 being the worst possible pain). Although the record reflected that the pain rated a pain level of 10 at 1:15 PM and 2:14 PM and a pain level of 8 at 3:55 PM, interventions to address the pain were not documented. Further review of the record dated 7/28/16 indicated the patient rated pain level of 5 or 6 at 4:42 PM, 6:30 PM, 8:10 PM, and 8:30 PM. The record failed to reflect that the patient's level of pain was addressed and/or rationale for not addressing it.
   Record review and interview with the Assistant Director of Quality on 6/4/18 at 11:30 AM stated the patient's vital signs did not support the reported pain level.
   Patient #4 presented to the ED on 8/23/16 at 7:32 PM after falling while getting out of the shower with complaints of lightheadedness. A pain assessment at 7:32 identified the patient

rated pain as a 4 on a pain scale of 1-10. Review of pain assessments dated 8/24/16 at 7:30 AM, 11:45 AM, 1:33 PM, and 2:15 PM indicated that the patient had a pain level of 10 and at 3:33 PM and at 4:00 PM had a pain level of 6. Review of the clinical record dated 8/24/16 at 12:54 PM indicated that the patient was complaining of hand pain and the daughter was asking for a morphine drip. Review of the MAR and progress notes failed to reflect that the patient's pain had been addressed.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

8. Based on clinical inspection of Radiology Services the hospital failed to ensure that safety precautions were maintained. The findings include the following:
   a. On May 10th and 11th an inspection team from the Connecticut Department of Energy and Environmental Protection's (DEEP), Radiation Division, conducted an inspection of Waterbury Hospital. The scope of the inspection was to ensure compliance with Section 19-24-1 through 19-24-14 "Radiation Sources and Radioactive Material" and Section 19-25a-1 through 19-25a-5 of our Administrative Regulations and Section 19-13-D3 of the Connecticut Public Health Code. Radiation Control Procedure 501, Revision One "Inspections of Hospital Nuclear Medicine and Radiology Programs" was utilized for the inspection.

      During the scope to the inspection the following violations were noted:

      Section 19-24-5 Maxim Doses:

      Paragraph (c) subparagraph (3) "No allowance shall be made for the use of protective clothing or equipment or particle size except as specifically approved by the department."

      Contrary to this, this has not been done. However, Waterbury Hospital sent to the department a letter dated February 14, 2018, to request such an allowance, however the Agency responded with a Request for Additional Information (RAI) in a letter dated March 26, 2018. Waterbury Hospital has yet to respond to the RAI's, to seek approval from the department.

      Section 19-24-8 Radiation Information Labeling:

      Paragraph (4) "Airborne Radioactive Area" (a) As used in section 19-24-1 to 19-24-14 inclusive Airborne Radioactivity Area means any room, enclosure or area in which airborne radioactive materials exist in concentrations in excess of the amounts specified in Appendix B, Table 1, Column 1, 10 CFR 20 or any room enclosure or area in which airborne radioactive material exists in concentration which averaged over the number of hours in any week during which individuals are in the area exceed 25% of the amount specified in

THE FOLLOWING VIOLATION(S) OF THE REGULATIONS OF CONNECTICUT STATE AGENCIES AND/OR CONNECTICUT GENERAL STATUTES WERE IDENTIFIED

appendix B Table 1, Column 1 of 10 CFR 20."

(B.) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "Caution Airborne Radioactivity Area".

Contrary to this the room in which Xe-133 gas is utilized was not posted as such, while the Xe-133 gas lung study was being performed.

Section 19-24-7 Surveys:

(A. (1.) As used in section 19-24-1-19-24-14 inclusive "survey" means an evaluation of the radiation hazards incident to the receipt, transfer, possession, manufacture, storage, use, operation, handling, transportation or disposal of radioactive materials or other sources of radiation under a specific set of conditions. Where appropriate, such evaluation shall include a physical survey of the location of materials and equipment and measurements of levels of radiation or concentrations of radioactive material present.
(2. Each owner of an installation shall make or cause to be made such surveys as may be necessary to comply with sections 19-24-1 through 19-24-14 inclusive.
(3.) The adequacy of surveys shall be subject to the review of the department's representatives.
(B.) Each owner shall maintain records showing the results of the surveys.

Calibration records for the Victoreen instrument utilized to measure Xe-133 gas could not be reproduced. Additionally, at one time the instrument was source response checked daily/prior to use but this practice was stopped. Therefore, it was determined that a proper measurement of radiation concentrations were not taken. Also, Xe-133 gas is heavier than air. The instrument is placed at a breathing zone level. Consideration might be taken into placing the instrument in a location more indicative of a true measurement of the airborne concentrations in the room (floor).
Observations:
(1. Information/calculations concerning airborne concentrations of radioactive material are still listed in Maximum Permissible Concentrations (MPC's). MPC's were replaced by Derived Airborne Concentration values in the early 1990's.
(2. Annual Audit- 10 CFR 20, Section 20.1101 "Radiation Protection Program" subpart (C) states: "The license shall periodically (at least annually) review the radiation protection program content and implementation." The only audit the program performs is a quarterly audit, which does not meet the requirements of this section. It was pointed out to the Radiation Safety Officer (RSO) that he should utilize NRC NUREG 1556 Volume 9, Specific Guidance for Medical Licensees, Appendix L, "Annual Program Audit" as a guide for his annual program audit.
(3. Observed Nuclear Medicine Tech in two posted radioactive material areas without wearing proper (whole body) dosimetery.

Barnett, Marylin

From: Cordeau, Sue <Sue.Cordeau@wtbyhosp.org>
To: Barnett, Marylin
Sent: Wednesday, August 22, 2018 9:41 AM
Subject: Read: Waterbury Hospital

Your message

To:
Subject: Waterbury Hospital
Sent: Wednesday, August 22, 2018 9:41:15 AM (UTC-05:00) Eastern Time (US & Canada)

was read on Wednesday, August 22, 2018 9:40:56 AM (UTC-05:00) Eastern Time (US & Canada).

Approved
8/30/18
SHN

Waterbury Hospital
WaterburyHEALTH

August 29, 2018

Susan H. Newton, RN, BS
Supervising Nurse Consultant
Facility Licensing and Investigations Section
State of CT, Department of Public Health
410 Capital Avenue
Hartford, CT 06134-0308

Dear Ms. Newton:

I am in receipt of your amended violation letter dated August 22, 2018 identifying the violations of the Regulations of Connecticut State Agencies and/or General Statutes of Connecticut found during the Department of Public Health unannounced visits made to Waterbury Hospital beginning on April 23, 2018 and concluding on June 4, 2018. Waterbury Hospital makes its best efforts to operate in full compliance with both state and federal laws and regulations. Nothing included in this plan of correction is an admission otherwise. Waterbury Hospital submits this plan of correction in order to comply with its regulatory obligations and does waive any objects or rights of appeal for any of the allegations contained in the department's letter dated August 22, 2018.

Also per your email dated August 21, 2018 I received your acknowledgement the office conference scheduled for September 11, 2018 at 1:00 PM in the Facility Licensing and Investigations Section of the Department of Public Health, Hartford CT may be conducted via a conference call versus on-site visit.

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (c) Medical Staff (2)(3).

1. Based on a review of the clinical record, staff interviews, and a review of the hospital's policies and procedures for one of three sampled newborn infants (Patient #22), the facility failed to obtain a physician's order that directed one type of diet and/or failed to document that education was provided regarding the use of supplementation in accordance with the hospital's policies and procedures. The findings included:
   a. Review of the clinical record identified Patient #22 was delivered on 4/23/18 at 3:19 PM. Physician's orders dated 4/23/18 at 3:35 PM directed breastfeeding with formula supplementation. Interview with the Director of Women's Health Services on 4/27/18 at 10:00 AM identified the initial diet order for the infant should have directed one feeding choice, as a medical indication for supplementation was not identified.
   b. Review of the nutritional flow sheets dated 4/24/18 and 4/25/18 indicated formula supplementation was provided. The progress notes identified Patient #22 was cluster feeding and remained irritable after nursing. Interview and review of the clinical record with the Director of Women's Health Services on 4/27/18 at 10:15 AM indicated that the clinical record failed to identify that education was provided to the mother regarding feeding behaviors and the risks of supplementation in accordance with the hospital policy. The hospital policy entitled breastfeeding directed in part that breastfeeding is the normative and optimal feeding method for infants. Formula supplementation should be avoided unless medically indicated. The policy further directed if supplementation was requested by a breastfeeding mother, she would be assessed as to the reasons for her request, educated about normal newborn feeding behaviors and requirements, counseled about the risks of supplementation to her infant, and how to protect her milk supply. The registered nurse would provide said counseling and document the information in the clinical record.

Measures to prevent recurrence:

1a. The FBC breast feeding policy was originally revised on March 16, 2018 with education to staff completed. During the week of May 28, 2018 staff meetings were held for the FBC and SCN staff. The Director, Women's Health Services re-educated the staff on the requirement that the maternal feeding plan MUST match the diet order. This requirement was also addressed with the providers on May 22, 2018 during their OB-GYN business meeting. To ensure on-going compliance effective May 1, 2018 the Lactation Consultant or designee audits all newborn records to ensure the diet order matches the maternal feeding plan. One to One feedback is provided if an outlier is identified. Audit results are reviewed monthly with the breast feeding committee and the FBC staff. Due to the audit results on August 24, 2018 the Director, Women's Health Services met with the Breast Feeding Committee and discussed opportunities for improvement. Effective August 27, 2018 with an anticipated end date of September 15, 2018 the FBC and SCN staff including the pediatric PAs will be re-educated via a self- learning

packet with signage on the following points: For those mothers wishing to breast feed, the newborn diet order will be entered as breast feeding ad-lib, if the mother request formula during the encounter an additional breast feeding with formula supplementation order will be entered. Audits will continue until compliance is sustained.
Effective date of correction action plan: May 28, 2018
Responsible person by title: Director, Woman's Health Services

Measures to prevent recurrence:
1b. The FBC breast feeding policy was originally revised on March 16, 2018 with education to staff completed. During the week of May 28, 2018 staff meetings were held for the FBC and SCN staff. The Director, Women's Health Services re-educated the staff on the revised policy requirement if supplementation is requested by a breastfeeding mother, she will be assessed as to the reason for her request, educated regarding normal newborn feeding behaviors and counseled about the risks of supplementation to her infant and stimulating her milk production and the assessment, education will be documented in the medical record. To ensure on-going compliance effective May 1, 2018 the Lactation Consultant or designee audits all newborn and maternal records to ensure the diet order matches the maternal feeding plan and that appropriate education is provided and supportive documented in the record IF the mother requests supplemental feedings. One to One feedback is provided if an outlier is identified. Audit results are reviewed monthly with the breast feeding committee and FBC staff. Due to the audit results on August 24, 2018 the Director, Women's Health Services met with the Breast Feed Committee and discussed opportunities for improvement. Effective August 27, 2018 with an anticipated end date of September 15, 2018 the FBC and SCN staff including the pediatric PAs will be re-educated via a self- learning packet with signage on the requirement for breast feeding mothers requesting to supplement she must be: assessed as to the reason for her request, educated regarding normal newborn feeding behaviors and counseled about the risks of supplementation to her infant and stimulating her milk production and the assessment, education must be documented in the medical record. Audits will continue until compliance is sustained.
Effective date of correction action plan: May 28, 2018
Responsible person by title: Director, Woman's Health Services

<u>The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff 92)(B) and/or (i) General (6).</u>

2. *Based on a review of the clinical record, staff interviews, and a review of the hospital's policies and procedures for one sampled patient who underwent a caesarean section (Patient #13), the facility failed to ensure an internal fetal monitor was not retained. The finding included:
   a. Review of the clinical record identified Patient #13 was admitted to the hospital on 4/2/18 at 2:21 AM at thirty eight weeks gestation with spontaneous rupture of membranes. At 7:43 AM fetal bradycardia was identified and an internal fetal scalp electrode was inserted to assess fetal well-being. Fetal bradycardia continued and

Patient #13 underwent an emergency caesarean section on 4/2/18 at 7:57 AM secondary to fetal distress. Due to the emergent nature of the surgery an instrument count was not conducted. Abdominal imaging was completed at the close of the surgical case prior to the patient leaving the operating room, per hospital procedure. The radiologist notified MD #11 thirty minutes after the case that a wire metallic object was located in the mid upper abdomen. A repeat film was completed that confirmed a retained metallic device. Patient #13 was taken back to the operating room on 4/2/18 at 11:16 AM under general anesthesia to remove a fetal scalp electrode.

Interview with MD #11 on 5/2/18 at 10:20 AM indicated abdominal imaging was conducted after the patient was closed. MD #11 left the operating room prior to obtaining the results of the abdominal film. MD #11 identified she called the family birthing center and received a verbal report from the unit secretary that the abdominal film did not reveal a retained foreign body. MD #11 indicated approximately thirty minutes after the procedure the radiologist informed her of a possible retained metallic device. After imaging was conducted a second time to confirm the foreign body, the patient was taken to the operating room for the removal of the scalp electrode. MD #11 identified that typically the scalp electrode is removed prior to the start of the cesarean section, however due the emergent nature of this case it was not. MD #11 observed the internal fetal electrode when removing the infant from the uterus and cut the wire and handed it to the scrub nurse. MD #11 then removed the scalp electrode and placed it on the lap pad. MD #11 indicated when she removed the lap pad from the patient's abdomen the electrode likely fell into the abdomen.

Interview with Surgical Technician #1 on 5/1/18 at 1:00 PM identified that an internal monitor was not part of the surgical count. Surgical Technician #1 indicated although the wire was collected she did not know that the electrode was part of the device, therefore, she did not communicate to the surgical team that it was missing.

Interview with the Vice President of Performance Improvement on 5/2/18 at 11:00 AM indicated that subsequent to the event the family birthing center count sheet was revised to include the removal of the fetal scalp electrode. The count policy was revised to direct that the physician cannot leave the operating room prior to communicating with the radiologist when imaging was conducted to ensure that a foreign body was not retained.

The hospital policy entitled Count Policy failed to identify that counts may be omitted for life threatening emergent procedures and that the patient or the practitioner cannot leave the operating room until a reading was received from the radiologist when imaging was conducted.

Measures to prevent recurrence:

2a. The Directors of Performance Improvement and Risk Management were notified of the event by the Director, Women's Health Services on April 2, 2018. On April 3, 2018 a Root Cause Analysis was initiated and completed on May 1, 2018. The case was reviewed by the Serious

Events Committee on April 4, 2018. The OR Count Policy was revised on April 16, 2018 to include: Counts may be omitted when followed by a postoperative x-ray for life threatening emergency procedures. The patient and practitioner shall not leave the OR until a reading is received from the radiologist or a preliminary "wet read" is performed by the practitioner. The count sheet was amended to include a field to confirm removal of FSE or IUPC in its entirety. Beginning April 26, 2016 ending on June 6, 2018 The Director of Women's Health Services re-educated the staff with signed acknowledgment on the count policy and OR count sheet revisions Effective 04/26/2018 The OB-GYN section chair sent an email to all OB-GYN providers re-educated them on the revised count policy and OR count sheet.

Effective date of corrective action plan: 04/26/2018

Responsible person by title: Director, Women's Health Services

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (d) Medical Records and/or (e) Nursing Services (1).

3. Based on clinical record reviews, review of facility documentation and interviews for one of three sampled patients (Patient #6) who were a fall risk, the facility failed to ensure an assessment was performed following an unwitnessed fall. The findings include:
   a. Patient #6 was admitted on 1/3/18 from a SNF for evaluation of increased agitation and violent behaviors. Patient #6's past medical history included diabetes, traumatic brain injury, below knee amputation, substance and alcohol abuse and major depression. The clinical record identified the patient's activity status as bathroom privileges and use of a prosthetic leg. The clinical record identified the patient was assessed at risk for falls. A physician's order dated 1/3/18 directed safety checks every two hours.

   Review of the clinical record identified on 1/6/18 safety checks was documented every two hours this included chair/bed alarm and call bell within reach. The nursing note dated 1/6/18 at 5:11AM identified the patient had stated he/she had an unwitnessed fall on 1/6/18 at approximately 1:00AM and complained of right shoulder pain. The note identified the patient was put in a reclining chair, the wheelchair removed and prosthetic leg placed in the room hall. The note further identified Patient#6 had a witnessed fall at 4:00AM, the patient was assisted back to bed, becoming increasingly agitated and refusing to stay in bed. After physician notification an order directed X-ray of the right shoulder and CT scan of the head.

   Review of the clinical record failed to identify documentation that the patient was assessed following the unwitnessed fall.

   The CT scan of the head dated 1/6/18 reported negative findings; X-ray of the right shoulder dated 1/6/18 reported no fracture, question of joint separation and recommendation for clinical correlation. The orthopedic consult dated 1/9/18 identified right shoulder joint separation, no surgery intervention required and to wear sling.

In an interview on 4/27/18 at 11:40AM, RN#3 identified on 1/6/18 Patient #6 informed him that he/she had a fall at the end of the hall. RN#3 had noted urine on the floor in the area of where the unwitnessed fall had occurred. RN#3 further identified he put away the patient's prosthetic leg and wheelchair and could not recall if he had performed a full physical assessment. RN#3 also stated that Patient #6 knew how to turn off the bed alarm and somehow got out of the bed, retrieved the prosthetic leg and attempted to get out of the room where he was witnessed to have another fall. RN#3 further identified the patient was assisted back to bed, was verbally abusive and complained of shoulder pain.

In an interview on 4/27/18 at 2:00PM, the Risk Manager (Manager#2) indicated the facility investigation identified the patient had an unwitnessed fall at 1:00AM and a subsequent fall at 3:45AM. Manager #2 identified the post fall assessment would be located in the clinical record.

Review of the facility fall prevention policy identified in part the post fall assessment, interventions and documentation includes assessing the patient's condition and to notify the MD of the fall.

Measures to prevent recurrence:
3a. This is a very unfortunate patient with a history of a TBI who was extremely difficult to manage due to violent/explosive/manipulative behavior. To clarify the Fall Prevention hospital policy post fall assessments, interventions and documentation section includes: "*assessing the patient's condition and determine if the patient can be safely assisted off of the floor to a bed or stretcher;* notify MD/APRN/PA of the fall and document the fall in the medical record. On January 6, 2018 at approximately 01:00 patient #6 was back in the wheelchair unassisted when he notified RN # 3 of the unwitnessed fall in the patient lounge. RN#3 did document the unwitnessed fall in the medical record and further noted that patient #6 was complaining of right shoulder pain. RN # 3 failed to notify a provider of this fall/patient complaint. Patient #6 was promptly evaluated by a provider with diagnostic testing ordered, including a right a shoulder x-ray following the January 6, 2018, 03:45 witnessed fall. On April 26, 2018 the Patient Care Manager of the med-surg floor provided re-education to RN #3 that a provider should have been notified of patient #6 unwitnessed fall to evaluate the right shoulder complaints. To ensure on-going compliance patient falls are reviewed monthly by the Fall Committee. Opportunities for improvement are discussed with follow-up provided to the staff. Clinical staff receive mandatory fall prevention education which include post fall requirements upon hire and yearly thereafter via a Healthstream module.
Effective date of corrective action plan: 04/26/2018
Responsible person by title: Chief Nursing Officer

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (i) General (6) and/or (l) infection control (1).

4. Based on observations, facility documentation and interviews the facility failed to ensure the auto instrument washer/disinfector and ultrasonic cleaner were tested according to manufacturer guidelines. The findings include:
   a. During tour of the Central Sterile Department on 4/23/18 review of the automated washer disinfector log sheet for the test object surgical instrument (T.O.S.I.) blood soil test and the Sono check log sheet identified documentation for testing on 1/4/18, 1/12/18, 1/30/18, 2/5/18, 2/15/18, 3/5/18, 3/19/18, 4/2/18 and 4/19/18. The log sheets identified 'Pass' for each date tested and initialed by the Central Sterile Tech manager.
   In an interview on 4/23/18 at 1:40PM the Central Sterile Tech manager acknowledged that the tests should be performed weekly but has not been able to maintain this.

   According to the Association for the Advancement of Medical Instrumentation (AAMI) guidelines weekly TOSI testing is required to evaluate the cleaning effectiveness of the automated instrument washers.

   The facility was unable to provide a policy for testing the effectiveness of the washer/ disinfector and ultrasonic cleaner, subsequent to surveyor inquiry policies were formatted for the same.

Measures to prevent recurrence:
4a. On April 24, 2018 the Assistant Director, Central Sterile Supply and the Infection Prevention Specialist developed the Quality Checks for The Washer/Disinfectors and Ultrasonic Cleaners policy. The policy language states TOSI testing is performed weekly on each washer disinfector with SonoCheck testing to be performed on each ultrasonic cleaner. Effective April 24, 2018 the Assistant Director, CSS or the CSS inventory coordinator performs the weekly testing. To ensure compliance the weekly checks are documented in a separate log sheet for the washer and ultrasonic machines.
Effective date of correction action plan: April 24, 2018
Responsible person by title: Assistant Director, Central Sterile Supply

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (e) Nursing Services (1) and/or (i) General (6).

5. Based on medical record review and interviews for 1 (P#14) of 4 patient reviewed for restraint use and/or constant observation the hospital failed to ensure constant observation was provided as according to hospital policy. The findings include:
   a. Patient (P) #14 was admitted on 4/13/18 to the behavioral health unit (BHU) from the Emergency Department (ED) after expressing suicidal ideation (SI). P#14's history included prior ED visits due to SI, recent heroin and Phencyclidine (PCP) use, assaultive behavior, hyper sexuality and promiscuous behavior including prostitution.

Initial and subsequent suicide risk assessments identified P#14 expressed no SI and remained safe with checks every 15 minutes. P#14 remained on checks every 15 minutes until 4/19/18 at which time P#14 was placed on constant observation (CO) after physically assaulting a staff member.
During interviews with Register Nurse (RN) #1,Security Officer (SO) #1, Behavioral Health (BH) Technician #1 and BH Technician #2 the staff indicated SO#1 was assigned constant observation for P#14 and was positioned outside P#14's room in the hallway. They indicated SO#1 was not observing P#14 from inside his/her room because P#14 had exhibited paranoid, accusatory, hypersexual behaviors towards staff including removing his/her clothing. P#14 remained in his/her room in bed at all times between 10:00 PM and 11:20 PM. SO#1 indicated P#14 remained within the line of sight at all times.

Hospital Patient Observation policy indicated the purpose of a BH constant staff companion was to maintain patient safety and the safety of others. The policy further indicated when a patient was under constant observation (CO) the patient should remain within arm's reach of staff members at all times.

In addition, although P#14's physician orders and treatment plan identified P#14 required constant observation, the treatment plan failed to indicate the rationale for modifying aspects of the hospital policy to treat P#14's individualized needs.

Measure to prevent recurrence:
5a. During daily huddles beginning on April 23, 2018 ending on April 30, 2018 the Assistant Director, Behavioral Health Services or designee provided re-education to the staff on the following requirements for patient's requiring a constant staff companion (CSC): The staff member performing the observation MUST be within an arm's reach at all times; if the patient requires a CSC who is demonstrating behaviors that requires more space between patient and staff the rationale is documented in their treatment plan; in this scenario the patient MUST always remain within eye sight; same gender staff member will be assigned to any a patient exhibiting sexually inappropriate behavior. The Center for Behavioral Health Patient Observation policy was revised on April 24, 2018 to include the following requirements: document in the patient treatment plan the rationale for not being within arm's reach of a patient and assigning same gender staff for patients exhibiting sexually inappropriate behaviors. To re-enforce the education requirements effective August 23, 2018 with an anticipated completion date of August 31, 2018 all behavioral health staff will be re-educated via a self-learning packet with signage on the guidelines for constant staff companion observation.
Effective date of corrective action plan: April 23, 2018
Responsible person by title: Chief Nursing Officer

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (c) Medical Staff (2) and/or (4) (A).

6. Based on observation during tour, clinical record review, and interviews, the facility failed to ensure the privacy of one patient (#8) during a psychiatric consultation. The

finding includes the following:

a. Review of Patient #8's clinical record indicated that the patient was seen in the outpatient behavioral health clinic for medication management. Review of the note dated 2/26/18 indicated that the patient was evaluated by MD #5, noted the patient was in a wheelchair and was feeling ok. The patient was alert and fully oriented, had good insight and good judgement.
Interview with MD #5 on 4/24/18 at 11:00 AM stated when he consulted with the patient on 2/26/18, the patient's wheelchair did not fit through the doorway so he spoke to him/her while the patient was in the hallway. Interview with Patient #8 on 5/21/18 at 11:00 AM indicated that the patient knew his/her wheelchair would not fit in MD #5's office and had told this to the secretary on arrival to the clinic. Patient #8 stated he/she sat in the hallway with only his/her legs in the office and head down crying during the evaluation.

A tour of the facility was conducted with the Director of the program who indicated that there are some doorways in the facility that are too narrow for a wheel chair and there are other open rooms on the floor that are to be used. The Director indicated that the facility protocol is for the practitioner to move to another office down the hall and that there are three that are open for use.

Measures to prevent recurrence:
6a. On April 24, 2018 the Director, Ambulatory Behavioral Health re-educated MD#5 on the following: wheelchair accessible rooms are in the immediate area of his office and re-enforced the requirement a handicap accessible room must be utilized when examining/treating a patient that cannot enter an office/examination room due to a wheelchair or other assistive devices. In addition on May 18, 2018 the provider completed a HIPPA course via a Healthstream module.
Effective date of corrective action plan: April 24, 2018
Responsible person by title: Director, Ambulatory Behavioral Health

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (d) Medical records (3) and/or (e) Nursing service (1).

7. Based on a review of clinical records and interview, for one of three patients reviewed for pain (Patient #4), the facility failed to ensure the patient's pain was addressed. The findings include the following:
   a. Patient #4 presented to the ED on 7/28/16 at 12:42 PM after a fall with a question of a syncopal episode. The record reflected that the patient was noted to be diaphoretic, slightly confused, and complained of abdominal pain (pain rated as a 10 on a scale of 1-10 with 10 being the worst possible pain). Although the record reflected that the pain rated a pain level of 10 at 1:15 PM and 2:14 PM and a pain level of 8 at 3:55 PM, interventions to address the pain were not documented. Further review of the record dated 7/28/16 indicated the patient rated pain level of 5 or 6 at 4:42 PM, 6:30 PM, 8:10 PM, and 8:30 PM. The record failed to reflect that the patient's level of pain was addressed and/or rationale for not addressing it. Record review and interview

with the Assistant Director of Quality on 6/4/18 at 11:30 AM stated the patient's vital signs did not support the reported pain level.
Patient #4 presented to the ED on 8/23/16 at 7:32 PM after falling while getting out of the shower with complaints of lightheadedness. A pain assessment at 7:32 identified the patient rated pain as a 4 on a pain scale of 1-10. Review of pain assessments dated 8/24/16 at 7:30 AM, 11:45 AM, 1:33 PM, and 2:15 PM indicated that the patient had a pain level of 10 and at 3:33 PM and at 4:00 PM had a pain level of 6. Review of the clinical record dated 8/24/16 at 12:54 PM indicated that the patient was complaining of hand pain and the daughter was asking for a morphine drip. Review of the MAR and progress notes failed to reflect that the patient's pain had been addressed.

Measures to prevent recurrence:
7a. This complaint investigation is related to one patient with two Emergency Department visits that occurred in April and May of 2016. The two RNs who failed to document the patient's level of pain was addressed and/or rationale for not addressing are no longer employed at the hospital so we were unable to provide one to one re-education. Effective January 5, 2018 all ED RNs were assigned an ED pain management compliance re-education module in Healthstream. The education was completed on February 6, 2018. Effective February 1, 2018 the Nursing Director, Emergency Services or designee audits 30 random ED records to ensure ED Pain Management Compliance. One to one follow-up is provided if a deficiency is identified. The audit results are reported quarterly at the Performance Improvement Safety Committee for monitoring and oversight.
Effective date of correction action plan: January 5, 2018
Responsible person by title: Nursing Director, Emergency Services

The following is a violation of the Regulation of Connecticut State Agencies Section 19-13-D3 (b) Administration (2) and/or (f) Diagnostic and therapeutic facilities and/or (i) General (6).

8. Based on clinical inspection of Radiology Services the hospital failed to ensure that safety precautions were maintained. The findings include the following:
   a. On May 10th and 11th an inspection team from the Connecticut Department of Energy and Environmental Protection's (DEEP), Radiation Division, conducted an inspection of Waterbury Hospital. The scope of the inspection was to ensure compliance with Section 19-24-1 through 19-24-14 "Radiation Sources and Radioactive Material" and Section 19-25a-1 through 19-25a-5 of our Administrative Regulations and Section 19-13-D3 of the Connecticut Public Health Code. Radiation Control Procedure 501, Revision One "Inspections of Hospital Nuclear Medicine and Radiology Programs" was utilized for the inspection.
   During the scope to the inspection the following violations were noted:

   Section 19-24-5 Maxim Doses:

OK per M.F. @ DEEP

Paragraph (c) subparagraph (3) "No allowance shall be made for the use of protective clothing or equipment or particle size except as specifically approved by the department."

Contrary to this, this has not been done. However, Waterbury Hospital sent to the department a letter dated February 14, 2018, to request such an allowance, however the Agency responded with a Request for Additional Information (RAI) in a letter dated March 26, 2018. Waterbury Hospital has yet to respond to the RAI's, to seek approval from the department.

Measures to prevent recurrence:
8a. On May 22, 2018 the chair radiation safety committee, radiation safety officer and chief operating officer drafted a response to the DEEP with the additional information requested. On June 18, 2018 the hospital received a letter from the DEEP approving the request to credit an allowance for use of protective clothing and equipment in calculating occupational dose to the whole body (dual badging). The allowance was retroactive to January 1, 2018.
Effective date of correction action plan: May 22, 2018
Responsible person by title: Radiation Safety Officer
Section 19-24-8 Radiation Information Labeling:

Paragraph (4) "Airborne Radioactive Area" (a) As used in section 19-24-1 to 19-24-14 inclusive Airborne Radioactivity Area means any room, enclosure or area in which airborne radioactive materials exist in concentrations in excess of the amounts specified in Appendix B, Table 1, Column 1, 10 CFR 20 or any room enclosure or area in which airborne radioactive material exists in concentration which averaged over the number of hours in any week during which individuals are in the area exceed 25% of the amount specified in appendix B Table 1, Column 1 of 10 CFR 20."

(B.) Each airborne radioactivity area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "Caution Airborne Radioactivity Area".

Contrary to this the room in which Xe-133 gas is utilized was not posted as such, while the Xe-133 gas lung study was being performed.

Measures to prevent recurrence:
B. Effective May 11, 2018 the Radiology Manager printed the appropriate airborne radioactive area signage, provided the signage to the nuclear techs and verbally educated the nuclear medicine technologists on the requirement to post the signage on the door during when Xe-133 gas is utilized for lung studies. Twenty six ventilation lung scans were performed from May 11, 2018 through August 27, 2018. To ensure compliance the radiology manager performed a random observation of 13 procedures

to ensure the appropriate signage was posted on the door 100% compliance was achieved.
Effective date of correction action plan: May 11, 2018
Responsible person by title: Radiology Manager

Section 19-24-7 Surveys:

(A. (1.) As used in section 19-24-1-19-24-14 inclusive "survey" means an evaluation of the radiation hazards incident to the receipt, transfer, possession, manufacture, storage, use, operation, handling, transportation or disposal of radioactive materials or other sources of radiation under a specific set of conditions. Where appropriate, such evaluation shall include a physical survey of the location of materials and equipment and measurements of levels of radiation or concentrations of radioactive material present.
(2. Each owner of an installation shall make or cause to be made such surveys as may be necessary to comply with sections 19-24-1 through 19-24-14 inclusive.
(3.) The adequacy of surveys shall be subject to the review of the department's representatives.

(B.) Each owner shall maintain records showing the results of the surveys.
Calibration records for the Victoreen instrument utilized to measure Xe-133 gas could not be reproduced. Additionally, at one time the instrument was source response checked daily/prior to use but this practice was stopped. Therefore, it was determined that a proper measurement of radiation concentrations were not taken. Also, Xe-133 gas is heavier than air. The instrument is placed at a breathing zone level. Consideration might be taken into placing the instrument in a location more indicative of a true measurement of the airborne concentrations in the room (floor).
Measures to prevent recurrence:
(A) (1) (2) (3) and B: Effective August 22, 2018 the Radiology Manager sent at email to the Chief Interpreting Nuclear Medicine Radiologist at the recommendations of the hospital's radiology safety officer to remove the Victoreen instrument that measures Xe-133 gas from service and transition to Tc-99m DTPA for ventilation lung scans. Anticipate the transition to Tc-99m DTPA on or before October 1, 2018.
Effective date of correction action plan: August 22, 2018
Responsible person by title: Radiology Manager

Observations:

(1. Information/calculations concerning airborne concentrations of radioactive material are still listed in Maximum Permissible Concentrations (MPC's). MPC's were replaced by Derived Airborne Concentration values in the early 1990's.

Measures to prevent recurrence:
(1): Transition from Xe-133 gas and replace with Tc-99m DTPA for ventilation lung scans.
Effective date of correction action plan: October 1, 2018
Responsible person by title: Radiology Manager

(2. Annual Audit- 10 CFR 20, Section 20.1101 "Radiation Protection Program" subpart (C) states: "The license shall periodically (at least annually) review the radiation protection program content and implementation." The only audit the program performs is a quarterly audit, which does not meet the requirements of this section. It was pointed out to the Radiation Safety Officer (RSO) that he should utilize NRC NUREG 1556 Volume 9, Specific Guidance for Medical Licensees, Appendix L, "Annual Program Audit" as a guide for his annual program audit.
Measures to prevent recurrence:
(2): On June 26, 2018 an annual audit of the Radiation Protection Program was performed by a health physicist. Moving forward an audit will be performed annually.
Effective date of correction action plan: June 26, 2018.
Responsible person by title: Radiation Safety Officer

(3. Observed Nuclear Medicine Tech in two posted radioactive material areas without wearing proper (whole body) dosimetry.
Measures to prevent recurrence:
(3): On May 11, 2108 the day of the finding the nuclear medicine technologist was counseled by the Radiology Manger.
Effective date of correction action plan: May 11, 2018
Responsible person by title: Radiology Manager

Respectfully Submitted:

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